

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of claims:

- 1 (original): A process for preparing pharmaceutical granules which contain an active ingredient in the form of a salt, said process comprising the steps of:
- (a) providing a powder containing the active ingredient as a free base or acid, and
 - (b) agglomerating the powder by adding a granulation liquid to form granules;
- wherein step (b) is conducted in the presence of a neutralization agent capable of neutralizing the active ingredient, and for a sufficient amount of time to allow the active ingredient to become at least partially converted into a salt.
- 2 (original): The process of claim 1, wherein step (b) is conducted for a sufficient amount of time and in the presence of a sufficient amount of neutralization agent to neutralize substantially all of the active ingredient contained in the powder.
- 3 (currently amended): The process of claim 1 ~~or 2~~, wherein the free base or acid of the active ingredient contained in the powder has a water solubility at room temperature of less than 5 wt.-%.
- 4 (currently amended): The process of ~~any of the preceding claims~~ claim 1, wherein the salt formed by neutralizing the free base or acid of the active ingredient with the neutralization agent has a water solubility at room temperature which is at least 1 wt.-%.
5. (currently amended): The process of ~~any of claims 1 to 3~~ claim 1, wherein the salt formed by neutralizing the free base or acid of the active ingredient with the neutralization agent has a water solubility at room temperature which is at least twice as high as that of the free base or acid.

6 (currently amended): The process of ~~any of the preceding claims~~ claim 1, wherein the granulation liquid is an aqueous liquid.

7 (currently amended): The process of ~~any of the preceding claims~~ claim 1, wherein the granulation liquid comprises at least one organic solvent selected from alcohols, acetone and methylene chloride.

8 (currently amended): The process of ~~any of the preceding claims~~ claim 1, wherein the granulation liquid comprises at least one organic solvent selected from ethanol, methanol, isopropanol and mixtures thereof.

9 (currently amended): The process of ~~any of the preceding claims~~ claim 1, wherein the neutralization agent is provided as a component of the powder.

10 (currently amended): The process of ~~any of claims 1 to 8~~ claim 1, wherein the neutralization agent is provided as a component of the granulation liquid.

11 (currently amended): The process of ~~any of the preceding claims~~ claim 1, wherein step (b) is carried out in a mixer, high-shear mixer, fluid-bed granulator, or rotary granulator.

12 (currently amended): The process of ~~any of the preceding claims~~ claim 1, wherein the granulation liquid is added to the powder by spraying the liquid through a nozzle onto the powder.

13 (original): Pharmaceutical granules containing an active ingredient in the form of a salt, said granules being obtainable by a process comprising the steps of:

- (a) providing a powder containing the active ingredient as a free base or acid; and
- (b) agglomerating the powder by adding a granulation liquid to form granules;

wherein step (b) is conducted in the presence of a neutralization agent capable of neutralizing the active ingredient and for a sufficient amount of time to allow the active ingredient to become at least partially converted into a salt.

14 (original): The granules of claim 13, characterized in that they are substantially free of polymeric excipients such as polymeric binders and disintegrants.

15 (currently amended): The granules of claim 13 ~~or 14~~, comprising one or more additional excipients, preferably selected from the group of bulking agents, fillers, binders, surfactants, stabilizers, preservatives, antioxidants, disintegrants, coloring agents, taste masking agents, sweeteners, flavors, release modifiers, plasticizers, and compression aids.

16 (original): The granules of claim 15, comprising a surfactant selected from the group of tyloxapol, polysorbates, phospholipids, and vitamin E-TPGS.

17 (currently amended): The granules of ~~any of claims 13 to 16~~ claim 13, comprising an excipient with a water solubility at room temperature of at least 10 wt.-%.

18 (currently amended): The granules of ~~any of claims 13 to 17~~ claim 13, comprising an excipient selected from the group of sugars and sugar alcohols.

19 (currently amended): The granules of ~~any of claims 13 to 18~~ claim 13, characterized in that they are soluble in water or in a physiologically acceptable aqueous vehicle at room temperature to form a solution which is suitable for inhalation.

20 (original): The granules of claim 19, characterized in that they are dissolvable in water or in a physiologically acceptable aqueous vehicle within less than 30 seconds at room temperature.

21 (currently amended): The granules of ~~any of claims 13 to 20~~ claim 13, comprising an active ingredient selected from the group of salbutamol, levalbuterol, formoterol, fenoterol, salmeterol, bambuterol, brocaterol, tiotropium, oxitropium, ipratropium, lidocaine, procaine, cystein, cromoglycinic acid, beclomethasone, triamcinolone, amoxicillin, ceftibuten, cefoxitin, aztrenonam, colistin, tobramycin, doxycycline, sildenafil, vardenafil, barbituric acid derivatives, benzodiazepines, morphine, codeine, salicylic acid, and their derivatives, conjugates, isomers, epimers, diastereomers, or racemic mixtures.

22 (currently amended): The granules of ~~any of claims 13 to 21~~ claim 13, having a weight-average particle size between 100 and 800 μm .

23 (currently amended): A pharmaceutical composition, comprising granules according to ~~any of claims 13 to 22~~ claim 13.

24 (original): The pharmaceutical composition of claim 23, constituting a tablet prepared by compressing the granules and, optionally, further excipients.

25 (original): The pharmaceutical composition of claim 23, constituting a hard capsule filled with the granules and, optionally, further excipients.

26 (original): The use of pharmaceutical granules for the pulmonary delivery of an active ingredient.

27 (original): The use of claim 26, wherein the pharmaceutical granules are substantially free of polymeric excipients, such as polymeric binders.

28 (currently amended): The use of claim 26 ~~or 27~~, wherein the pharmaceutical granules are substantially free of insoluble excipients.

29 (currently amended): The use of ~~any of claims 26 to 28~~ claim 26, wherein the pharmaceutical granules contain an active ingredient in the form of a salt, and wherein the granules have been prepared by a process comprising the steps of:

- (a) providing a powder containing the active ingredient as a free base or acid; and
- (b) agglomerating the powder by adding a granulation liquid to form granules;

wherein step (b) is conducted in the presence of a neutralization agent capable of neutralizing the active ingredient and for a sufficient amount of time to allow the active ingredient to become at least partially converted into a salt.

30 (currently amended): The use of ~~any of claims 26 to 29~~ claim 26, wherein the granules are dissolved in an aqueous carrier to prepare a solution for inhalation.

31 (original): The use of claim 30, wherein the solution for inhalation is aerosolized with a nebulizer.